

Virginia Board of Pharmacy

Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range or not monitored	18VAC110-20-150		100
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
13. No biennial inventory, or over 30 days late	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained or monitored as required	18VAC110-20-240	will not be cited until 9/1/2010	250
16. Theft/loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. Non-sterile compounding not in compliance with USP 795	54.1-3410.2		250
22. Sterile compounding not in compliance with USP 797	54.1-3410.2		1000
23. Compounding using ingredients in violation	54.1-3410.2		1000
24. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or \$5000	50

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
25. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
26. Security of after-hours stock not in compliance	18VAC110-20-450		500
27. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250

Minor Deficiencies

If three (3) or more minor deficiencies are cited, a \$250 monetary penalty shall be imposed. Another \$100 monetary penalty will be added for each additional minor deficiency over the initial three.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
6. Current dispensing reference not maintained	18VAC110-20-170	
7. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	

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Minor Deficiency	Law/Regulation Cite	Conditions
8. Expired drugs in working stock or dispensed drugs being returned to stock not in compliance	18VAC110-20-200 18VAC110-20-355	10% threshold
9. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
10. Storage of will-call not in compliance	18VAC110-20-200	
11. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
12. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404 and 18VAC110-20-240	
13. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
14. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
15. Prescriptions do not include required information	54.1-3408.01 and 54.1-3410	10% threshold
16. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
18. Not properly documenting partial filling	54.1-3412, 18VAC110-20-255, and 18VAC110-20-320	
19. Offer to counsel not made as required	54.1-3319	
20. Prospective drug review not performed as required	54.1-3319	

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Minor Deficiency	Law/Regulation Cite	Conditions
21. Engaging in alternate delivery not in compliance	18VAC110-20-275	
22. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
23. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	
24. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
25. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold
Repackaging, specialty dispensing, compounding:		
26. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
27. Unit dose procedures or records not in compliance	18VAC110-20-420	
28. Robotic pharmacy systems not in compliance	18VAC110-20-425	
29. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
Hospital specific or long-term care specific:		
30. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
31. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	

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Minor Deficiency	Law/Regulation Cite	Conditions
32. After hours access or records not in compliance	18VAC110-20-450	10% threshold
33. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
34. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-550	
35. EMS procedures or records not in compliance	18VAC110-20-500	10% threshold
36. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
37. Maintaining floor stock in LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	